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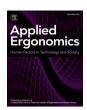
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PPE fit of healthcare workers during the COVID-19 pandemic

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ABSTRACT

Historically, PPE (Personal Protective Equipment) has generally been designed around the size and shape of an average European or US white man's face and body. There is little academic evidence to support anecdotal reports that women are at a greater disadvantage than men from ill-fitting PPE. This is especially relevant in healthcare settings where women make up at least 75% of frontline workers. The COVID-19 pandemic has exacerbated problems associated with the fit of PPE that until now have been mainly anecdotal. This research presents results and analysis of a quantitative and qualitative survey concerning the fit of PPE worn by 248 healthcare workers, in a variety of healthcare roles and settings, during the COVID-19 pandemic. The analysis of the survey results showed that women were less likely than men to feel safe carrying out their roles, with only 30.5% of women and 53.3% of men stating that they felt safe all of the time. A statistically significant link is made between women suffering more with poor fit than men with certain categories of PPE (gowns, masks, visors, goggles). Over four times as many women (54.8%) as men (13.3%) reported their surgical gowns being large to some degree and women were nearly twice as likely (53.5%) to experience oversized surgical masks than men (28.6%). However, it was recognized that PPE fit problems are not exclusive to women as many men also do not conform to the underlying shape and size of PPE designs. Survey results indicated that both sexes felt equally hampered due to the fit of their PPE and around a third of both women and men had modified their PPE to address fit issues. Oversized and modified PPE presents its own set of unintended consequences. Following strict processes for doffing and removing PPE is key to virus control but doffing modified PPE can fall outside of these processes, risking cross infection. In addition, wearers of critical items of PPE (such as respirators) currently undergo a "fit test"; however, fit does not reconcile with comfort and over-tightened PPE can cause headaches, discomfort and distraction when worn for long periods. Requirements and fit tests are also not setting-specific; qualitative responses from the survey give an indication that this must be a future consideration.

1. Introduction

Personal Protective Equipment (PPE) is often considered the last line of defence against risks (Ness, 2010). The UK's Health and Safety Executive (HSE) demands that all employers provide their employees who are at risk with "suitable PPE" and that this is only suitable if considerations include the "ergonomic requirements" of the wearer (HSE, 1992).

However, the design basis for most PPE has historically centered on the anthropometrics of average men from Europe and America (TUC, 2017) or, in the US specifically, based on data from the 1950–1960s.

Zuang and Bradtmiller's 2005 survey concluded that this historic data would not be adequate for the then current US workforce (Zhuang and Bradtmiller, 2005). Hsiao et al.'s study of anthropometrics of

firefighters confirmed that there are significant differences between men and women's anthropometrics, including head circumference, shoulder to grip length, palm width (Hsiao et al., 2014). In the UK, a more recent UK Trades Union Congress (TUC) survey in 2016 reported that, as a result of the design approach, most women and a proportion of men found issues with identifying appropriate PPE (TUC, 2017) and this "one size fits all" mentality does not work (Cooke, 2017) as PPE is no longer fit for purpose if it does not *fit*.

Fit issues, specifically around the head, also encompass differences in ethnicity and different ethnic groups may require different levels of customisation when it comes to PPE (Lee et al., 2017). Farkas et al. reinforced anthropometric distinctions between ethnic groups (Farkas et al., 2005). In further studies, such as that by Zhuang et al. widespread differences in head and face shapes across US civilian workers were

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highlighted, concluding that respirator design could be made safer through consideration of such findings (Zhuang et al., 2013). Ball et al. showed that "head related products" designed around a Western head were inappropriate for the Chinese form (Ball et al., 2010). Forrest considers similar observations with specific reference to Respiratory Protective Equipment (RPE); RPE standards are reliant on a tight face-fit seal (Forrest, 2001) and this is a clear example where ill-fitting equipment will not perform its task. In healthcare settings, especially during a pandemic such as COVID-19, this is vital as Healthcare Workers (HCWs) are already more susceptible to contracting healthcare-associated infections (Macintyre et al., 2014) without compounding the issue further through failure of their last line of protection. In 2014, during the Ebola epidemic, 1 in 10 healthcare workers contracted the virus, despite wearing PPE (Ahmad et al., 2018).

This study presents the results and analysis of a survey of healthcare workers' experience of fit of PPE during the COVID-19 pandemic. It examines the effect of PPE on their ability to carry out their role and their feelings around the level of safety experienced, whilst considering any differences between women and men.

2. Background

Poor fitting PPE has historically been a broader problem than for healthcare settings. PPE comprises multiple types of aid, e.g. hard hats, high visibility jackets, harnesses, safety footwear, eye protection and it is worn across industries such as construction, manufacturing, railways, fire and rescue. In 2017, Flynn et al. studied the available sizing of various types of PPE advertised by a range of manufacturers, concluding that sourcing the appropriate size of PPE is not easy for "alternative" sizes and shapes. Despite the availability of sizes increasing over time, size charts are seldom accessible and the marketing around such products is not indicative of a diverse workforce with images usually consisting of "white males of average size" (Flynn et al., 2017).

The TUC report of 2017 confirmed that it is commonplace for companies to procure men's PPE for women but in smaller sizes (TUC, 2017), but this unisex approach to PPE can lead to issues with fit and adequacy of protection. Responses to the TUC survey indicated that only 29% of women were wearing PPE that was specifically designed for women (TUC, 2017). Employees can find that they need to source their own PPE that suits their body or face, shape and size to ensure that it fits appropriately (Flynn et al., 2017), which undermines the legal requirements of the HSE for the employer to provide "suitable PPE" (HSE, 1992). It should also be noted that for staff employed in the NHS via national contracts, responsibility for PPE provision lies with the employing NHS Trust or Foundation (Cowper, 2020).

PPE is not only essential for ensuring the safety of healthcare workers, but, as established by Damery et al. (2009), its provision is a significant influence on employees deciding whether to attend work during a pandemic. Their 2009 survey of healthcare workers reported that 77.8% (n = 687) of those surveyed viewed the provision of PPE as a key intervention in attending work, second only to the provision of a vaccine (Damery et al., 2009), thereby indicating that PPE provides more than just physical protection for the workforce.

Defining "fit" can also prove problematic as it is subjective; agreement of fit usually lies with the user, with the exception of specific items such as "face fitting" respirators or masks which require the user to undergo a fit test.

An item may seemingly fit at a point in time, but is the item still said to "fit" if it becomes uncomfortable and causes bruising or other physiological damage?

3. Methods

A mixed methods survey was created with the aim of establishing the scale of fit problems for a range of PPE items across healthcare settings. Large scale surveys have been carried out previously on PPE; the aforementioned 2017 report from the TUC reported on PPE (in general) in relation to women based on two surveys conducted by the TUC (2655 responses) and Prospect (with the Women in Engineering Society) (3086 responses), but there have been no significant studies of PPE in healthcare settings which also capture any exacerbation of issues during a pandemic response.

Research questions were constructed to establish the range and impact of fit issues related to PPE across a range of healthcare settings, considering how any impacts differ by sex. More specifically, "Do people working in healthcare settings experience problems with the fit of their PPE?" If so,

- i. What are the problems?
- ii. Do they differ by sex?
- iii. Are these problems perceived to hamper their ability to carry out their role?
- iv. Are these problems perceived to lead to feelings of lack of safety when carrying out their role?

Sex is used as a differentiator as opposed to gender in order to capture any issues related to physical anthropometrics.

3.1. Sample population

203 women and 45 men completed the survey, totaling 248 responses. Appendix I Tables i and ii show the number of responses received by role type and healthcare setting respectively. Due to the breadth of healthcare roles, this field was presented as a free text response and categorized by the authors. For responses to questions about individual items of PPE, not all respondents wore every item; the number of wearers is denoted within the appropriate results.

The sample population size for the survey of n=248 is in excess of the n=100 required by Israel (2003) to achieve a 95% confidence interval where precision, $e = \pm 10\%$, variability, p = 0.5 for populations greater than 100,000 (Israel, 2003). The same is true where just women's responses are considered, though caution needs to be exercised when cursorily comparing women's and men's answers due to the greater than four-fold difference in sample population sizes ($n_{women} =$ 203 = 81.9%, $n_{men} = 45 = 18.1\%$). However, this is consistent with health worker employment ratios as noted in section 3.2.4. As advised in section 3.2.4, note that not all respondents wore every item, so precision is reduced for smaller numbers. Chi-square tests were used to test for independence between women and men specifically. Fisher's exact tests were used where numbers were too low for Chi-square assumptions to be valid. Chi-square testing is appropriate to indicate significance when sample sizes are unequal (Mchugh, 2013), as in the case of this study and is accompanied by strength indicator phi (φ) .

3.2. Survey

3.2.1. Question development

The initial survey contained a mixture of 26 quantitative and qualitative questions. These were based on the requirements of the research questions outlined above, the authors' experience and knowledge, available literature and reports in the media indicating that there were issues with PPE sizing and in particular for women, as outlined in sections 1 and 2. Content validity was assessed by experts in the field, including a primary care general practitioner, an accident and emergency consultant and an intensive care nurse. Items of PPE and potential issues were listed based on literature and scored out of 10 (Mackison et al., 2010) for their relevance to healthcare workers; there was a clear divide between those items showing relevance (score of 8 or above) and non-relevance (score of 2 or less) and those that were less relevant were not considered as part of the question set. Face validity was assessed with the same professionals via short interviews following completion of the initial survey. Respondents were given the opportunity to ask

questions or discuss queries around the survey questions.

3.2.2. Pilot study & survey development

A pilot survey was completed by a subset of 12 participants from varying roles and settings. Pilot participants were different to those that had assisted with validation of the above PPE list. Pilot respondents indicated that the survey should be deliberately kept brief to increase the likeliness of healthcare workers responding during the pressured pandemic period. As such, the original set of questions around problems with specific PPE was combined to form a single question with multiple discrete (independent) parts. Items of PPE listed within this question were further refined. A scaled response was used to capture the fit issues using the responses: Not worn; Much too small; A little small; Small in places; Just right; A little large; Very large; Large in places; followed by: Digs in; Causes bruising; Rubs/chafes; Other; No answer. Open-ended responses were added to all questions to ensure voluntary qualitative data could be captured. The final number of questions was reduced to 11: 5 quantitative questions relating directly to the research questions (4 of which included an option to add qualitative commentary), a single open-ended qualitative question requesting "further comments" and 5 questions related to demographics. Questions about fit had a Cronbach's alpha of 0.717 giving an acceptable level of reliability for the survey scale utilized.

3.2.3. Structure of survey

The survey was structured as per the questions shown in Table 1. All questions regarding wearing PPE related to the previous 2 weeks (to ensure applicability to the pandemic timeframe).

3.3. Distribution

The survey was distributed via various social media channels. The online survey was made accessible for a 3-week period from April 27, 2020 with the aim of achieving a sample size of at least 100 respondents to ensure a precision level (e) of at least 10%. It was important that the sex-split of the respondents was aligned with current split of NHS (National Health Service) employees being 77% women and 23% men (NHS Employers, 2015) though when considering specific roles, the percentage of women in nursing and health visitor roles is 89% (NHS Digital, 2019).

3.4. Analysis

Open-ended survey questions were analyzed using thematic analysis (TA) (Braun and Clarke, 2006, 2013, 2019, 2020). TA was selected because it fit the purpose of this project, bringing design alignment or coherence (Braun and Clarke, 2013; Willig, 2013) amongst the practically oriented and conceptually sensitive deployment and analysis of the qualitative portion of the surveys. TA, however, is not a singular or unified approach. Used in tandem with quantitative questions, this use of TA is more expressive of what Kidder and Fine (1987) suggested as

Table 1Survey questions.

No.	Question
1	Which of the following items of PPE have you worn and how did it fit? (14
	items listed with a range of scaled responses)
2	If any of your PPE didn't fit correctly, did you feel safe doing your job? (range
	of set responses, single allowed) with optional question to report any specific
	issues (free text)
3	Did poor fitting PPE hamper your ability to do your job? (range of set
	responses, single allowed) with optional question to report any specific issues
	(free text)
4–6	Have you had to modify or buy your own PPE for fit reasons, plus free text for
	any other comments
7–11	Demographics questions around sex, role, full or part time working pattern,
	earnings range

"small q" qualitative research wherein qualitative tools are more closely associate with post-positivist approaches as opposed to more subjective or reflexive accounts.

Using TA, two coders (the first and second author), independently reviewed open-ended survey responses for data familiarization followed by generation of initial codes. Subsequently, the two coders met to discuss these codes — in order to consider, question, and affirm their relevance and meaning in relation to the central research questions and alignment with quantitative results — prior to separately considering their grouping into themes. Together, themes were reviewed, defined, and named in dialogue with the quantitative elements. In discussion, and indeed as part of the purpose of the study to examine sex-based differences in PPE, it was acknowledged that the authors brought their own assumptions to the project. In this case, sex-based difference. As such, TA's flexibility — meaning that theory, literature, and knowledge cannot be entirely extricated from research and analytical practices enabled the authors to read sex differences into the qualitative data to meet the purpose of the study questions posed in section 3 and related quantitative results. For example, as part of the coding and thematizing process, a more inductive understanding inclusive of the entire data set was sought as evident in the theme of being hampered in their roles.

4. Results

This section presents quantitative and qualitative results, followed by a discussion and analysis in section 5. Comparative statistics have been analyzed using IBM® SPSS (IBM, 2017).

4.1. PPE fit by item

Respondents were asked to rate the fit of each item of PPE related to size by selecting from the following options: Not worn, Much too small, A little small, Small in places, Just right, A little large, Very large, Large in places. This was followed by further options about the impact of this, including: Digs in, Causes bruising, Rubs/chafes, Other, No answer. Results below are split by sex, with statistically significant differences being indicated. Results for "other surgical gown", "other barrier mask", "other respirator", "clogs/surgical footwear" and "surgical headwear" have not been included due to low numbers of responses. Table 2 indicates quantitative responses, Table 3 summarizes qualitative responses. All qualitative responses have been quoted verbatim for authenticity; it is recognized that some may contain grammatical errors.

4.2. Feeling safe

Respondents were asked if they felt safe doing their job if their PPE did not fit correctly over the preceding two weeks (to ensure that their responses were relevant to the pandemic period), and overall, only 34.7% indicated that they had felt safe all of the time or that their PPE fit. When considering sex differences, a greater proportion of men felt safe compared with women (women 30.5%, n = 62; men 53.3%, n = 24, χ^2 8.447, p = 0.004, ϕ = 0.185). When studying if PPE affected respondents' ability to do their jobs, 55.7% indicated that they had been hampered in their role, with no relationship between the response and sex.

Qualitatively, several issues infringed upon perceptions of safety. In addition to the items discussed in Table 3 (e.g., oversized and "flapping" aprons and gowns obstructing patient transfers, e.g. when moving from bed to bed), talking to patients through combination of visors, masks or respirators and also communicating with other team members complicated routine and unique duties. The impingement of one type of PPE on another presented an entangled PPE experience, for example, goggles on visors, masks on goggles, etc. One responded to this problem: "trying to cannulate difficult patients with glasses and face shield on." Mobility when wearing cumulative PPE was identified as a problem. The UK's Health and Safety Executive (HSE) specifically warns about such

Table 2PPE fit by item – Quantitative responses.

PPE	N_{women}	N_{men}	Key Statistics
Gloves	197	41	"Just right" fit reported by 74.6% women $(n = 145)$, 70.7% men $(n = 29)$, 73.6% overall.
Aprons	186	38	47.3% women (n = 88) and 42.1% men (n = 16) report the fit as "just right" (no statistical sex difference). Men were more likely to indicate a small fit to some degree; women 19.9%, n = 37;
			men 42.1%, $n=16$; $\chi^{2=}6.79$, $p=0.009$, $\phi=0.174$. 23.1% of women ($n=43$) and 15.8% mer ($n=6$) indicated large fit (no statistical sex difference).
Fluid Resistant Surgical Gowns	73	15	Women indicated large fit compared to men (women 54.8%, n = 40; men 13.3%, n = 2; χ^2 =7.523, p = 0.006, φ = 0.292). Men were more likely to find the fit "just right" (women 38.3%, n = 28; men 86.7%, n = 13; χ^2 =11.671, p = 0.001, φ = 0.364)
Surgical Masks	144	35	Large fit reported by women 53.5% (n = 77), men 28.6% (n = 9), (Fisher's exact indicates p = 0.0001) overall, 48.6%; Men find their masks to be smaller than women (women 5.6%, n = 8; men 25.7%, n = 9) (Fisher's exact indicates p =
FFP2/3 (Filtering Face Piece)	87	22	0.0001) "Just right" fit reported by 24.3% womer (n = 35), 34.3% men (n = 12). 16.1% (n = 40) of all users suffer from digging in or rubbing, chafing, bruising or digging in. A "just right" fit was reported by 49.4% women (n = 43), 63.6% men (n = 14) with
race rieces			no significant sex difference. A large fit was reported by 18.4% ($n=16$) and 18.2% ($n=4$) of women and men respectively. 35.6% of women ($n=31$) and 22.7% of men ($n=5$) reported chafing, digging in, rubbing or bruising (no significant sex
Respirators	21	5	difference) equating to 31.1% overall. No analysis completed due to low
Visor/Face Shield	118	15	numbers. A "just right" fit was more common in mer (women 45.8%, $n=54$; men 73.3%, $n=11$; $\chi 2=4.049$, $p=0.044$, $\phi=0.174$). A large fit was reported by 35.6% of
Goggles/Glasses	139	30	women. A "just right" fit was reported by 41.0% ($r = 57$) of women, men, 56.7% ($n = 17$) no significant sex difference. Women found fit to be large to some degree when compared with men (women 38.8%, $n = 54$; men13.3%, $n = 4$; χ^{2-7} , 127, $p = 0.008$, $\varphi = 0.205$).
Surgical Scrubs	107	24	χ 7.127, p = 0.008, φ = 0.205). 51.9% reported problems with their fit. There were no significant differences between women and men.

problems when it comes to selecting PPE, advising those that select PPE to ensure that multiple items are compatible when worn together (HSE, 1992).

4.3. Modifying or buying PPE

Of those that responded, 37.9% of women (n=77) and 33.3% of men (n=15) reported that they had modified their PPE to improve fit, giving no discernible difference between the sexes. A small number of respondents had purchased their own PPE in order to improve fit (women 6.9%, n=14; men 15.6%, n=7).

The most reported aspect of modifications involved over-tightening to secure aprons, masks and gowns. As noted in Table 3, gowns and

Table 3PPE fit by item – Qualitative responses

PPE	Qualitative Summary
Gloves	Good fit was only true if the correct size was available. Hal
	of the comments related to excessive moisture forming
	within the gloves resulting from poor fit and leading to sores, dryness or cracked skin.
Aprons	Two thirds of qualitative responses were concerned with
	how easily the aprons tore. Further issues pertained to
	aprons slipping to the side when moving patients and not
	providing protection at the rear when seated, for example when visiting a patient in a residential setting. Examples of
	references to aprons included the following: "huge and
	flappy"; "Aprons don't feel like they protect our scrubs at
Fluid Resistant	all"; and, "I don't feel the aprons add anything." Some healthcare workers found themselves having to
Surgical Gowns	adapt gowns by cutting thumb holes in sleeves that were
· ·	too long, wrapping the gown around themselves as they
	were too large, or shortening "to prevent trips."
	Participants also shared that they were not fully protected as their backs were exposed.
Surgical Masks	Masks were described as awkward to anchor, slipping
Ü	easily and regularly, and ill-fitting particularly across the
	bridge of the nose. One woman captured this succinctly:
	"Had to tape it down to the bridge of my nose to avoid constant slipping and digging on the glasses/goggles."
	Several commented that masks "gape at the side" whilst
	another indicated that masks were "itchy after a while with
	soreness around ears and facial rashes." One concern was
	the spreading of more "germs" to the face "as the mask was loose", which were then "fiddled with more frequently"
	and "necessitating hand-to-face movement." The elastic
	was highlighted by several as the cause of the problem with
	one person advising that the "original tie masks fit just right and stayed secure, however elasticated masks snap
	easily and the bands are too loose." The combination of
	masks and eye protection led to the eye protection fogging
	up for some. A further respondent stated that, "some staff
	keep taking the masks off due to irritation or feeling hot.' Indications were that on occasion, sizing depends on the
	quality or brand of the masks provided. Headaches and
	sweating were other reported side effects of mask usage.
FFP2/3 (Filtering Face	Fit was very dependent upon mask type/brand. One
Piece)	woman noted that she had, "Failed multiple fit tests for different masks before the current supply arrived. So did
	about 50% of my female colleagues." Another stated that
	she, "Had to be re-fit tested for FFP3 after passing fit test as
	steaming up glasses. Now have mask that fits but leaves rul marks on face." A third was told by her fitter that she would
	need to "gain a stone in weight" to help her mask fit.
	Feedback from a respondent who had mask-fitting
	responsibilities showed concern at the multiple tests that
	were often required to ensure a 'fit', stating, "if staff members can't get a pass on a mask very easily then we
	shouldn't be trying over and over again as in clinical
	practice they would probably spend less time putting the
	FFP3 mask than when mask fit tested." She went on to
	state, "The mask fitters within our Trust have massive concerns about other Trusts that are using qualitative
	testing methodology to mask fit as it is subjective and relies
	on staff to be truthful when they are putting a lot of
	pressure on themselves. It also relies on [sense of] taste
	which has been proven as a side effect of COVID," and as such, without a negative COVID-19 test, this aspect of the
	fit test cannot be relied upon.
Respirators	Issues were reported regarding incidence of "pressure
	sores" and "friction burns" with irritation beneath the eyes where the face is smaller.
Visor/Face Shield	Visors were found to fog up, and one woman "wished the
	visors weren't so large."
Goggles/Glasses	Responses focused on problems with misting up or falling
	off, especially when the head was lowered to look down. Some struggled due to requiring reading glasses to be worn
	beneath the goggles, with another indicating face
	protection was "uncomfortable behind my ears" due to
	simultaneously wearing glasses, goggles and mask. It
	wasn't clear to some whether this PPE was disposable, so
	(continued on next page)

Table 3 (continued)

PPE	Qualitative Summary
Surgical Scrubs	they relied on other staff members cleaning them thoroughly. Respondents advised that good fit depended on availability of sizing.

aprons were trimmed to avoid flapping, or to create new ties and some cut thumb holes in their gowns for practical access. Respondents further described using ear defenders, clips around the back of the head, homemade headbands with appropriately placed buttons, or other makeshift devices to alleviate problems around the ears from goggles, visors and masks; the use of tape to secure PPE was also reported.

5. Discussion

The study presented here corroborates mainstream reports that women are disadvantaged when it comes to the fit of PPE (Kleinman, 2020; Topping, 2020). However, this study confirms the extent of the gap between women and men and the types of PPE (within healthcare settings) for which the issues are more prevalent. The fact that a reasonable proportion of men are also disadvantaged is a significant and previously unconfirmed finding. This section discusses two key issues around PPE fit: firstly, how is "fit" determined, and should the regulations demand comfort and tolerability in equal measure alongside fit? Secondly, where PPE doesn't fit appropriately, what are the consequences? Some qualitative responses provided were deemed to be beyond the scope of this paper. However, these findings are included and discussed because they indicate larger scale problems with PPE in healthcare settings.

5.1. Fit versus comfort and tolerability

Following the results of a 2017 TUC survey (section 2), the TUC called on all employers not to buy from suppliers who failed to provide a full size range for both men and women and advised that women in particular "try on several sizes or types of PPE before it is issued to ensure best fit." This is not necessarily practical in fast moving work environments where employees may be required to wear PPE or 'go home.' Often, employees may have to choose the nearest or best fit, which might not *actually* fit. When this occurs, making personal adaptations appears a common response to ill-fitting PPE, which may or may not carry the same level of comfort or safety expected, experienced or needed.

In this study fit was found to be brand dependent and size problems were exacerbated when the nearest appropriate size was not made available. Some respondents reported that their (NHS) Trusts had changed procedures regarding mask fitting to improve outcomes, subsequently noting that it was the PPE that was problematic, not the methodology. One respondent indicated that it had become the responsibility of the wearer to complete fit-testing and colleagues were carrying out "self-fit checks". Some also described how their Trust had a 'one size fits all' approach to surgical gowns and others noting that the appropriate glove sizes were never available. Others, however, presented a more positive outlook, where a range of sizes of all PPE were accessible. There were general concerns noted over fit; one respondent noted, "With so much difference in sizing of PPE, you spend so much time fixing it to fit. And worrying in case it's not working due to fit."

During the COVID-19 pandemic, PPE fit was key for protecting frontline healthcare workers. Best fit may not be good enough, and if lack of fit has been a longstanding systemic problem for a large proportion of the population, acceptance of ill-fitting PPE may be the norm. When considering Respiratory Protective Equipment (RPE) in particular, figures reported for lack of fit in the current study were greater than those estimated in 2001 by Forrest (2001), who reported that between 10 and 20% of women would not be able to realise a satisfactory fit. The findings from this study corroborate results from Baig et al.'s 2010 study: whilst numbers were lower in their study (n = 159), the findings broadly show that males were more likely than females to indicate that the respirator was *comfortable* to wear (p = 0.003) (Baig et al., 2010). 'Fit' is key for functionality, but 'comfort' is rarely considered. One person responded that: "The PPE I wore was appropriate to guidance and technically fitted." This suggests that whilst PPE may fit, it may not be comfortable for the length of time it's intended to be worn. There is a likely element of 'comfort creep' where close fitting PPE such as FFP3 masks can appear comfortable in the first instance but is unlikely to be the case at the end of an 8-h period. This was also recognized by Baig et al.'s cohort (Baig et al., 2010); only 6% of whom reported that they would be able to bear wearing an appropriately fitting N95 respirator for a shift, even though it 'fit'.

Locatelli et al.'s 2014 study (Locatelli et al., 2014) of 17 subjects wearing FFP masks also confirmed that the fit test needed to consider the "comfort and tolerability" aspects of wear. This provided further indication that initial fit is not necessarily a gauge of sustained fit. Whilst current fit tests are clearly essential, PPE design that more readily passes the tests at the same level of safety is a vital step forward.

5.2. Unintended consequences

Wearing PPE that doesn't fit appropriately (section 4), can have unintended consequences. These can negatively affect the healthcare worker, the ability to maintain a sterile environment and ultimately, the patient and their clinical outcomes.

5.2.1. Physiological outcomes

One of the problems noted with close-fitting masks, in particular, is that they need to be pulled tight in order to maintain an effective seal (or to at least pass the fit test) and this can lead to a multitude of negative unintended consequences. Ong et al. (2020) corroborates the findings, stating "most healthcare workers" when donning new PPE experience headaches or a worsening of any established headache related issues. Thermal discomfort was also a problem reported by Ong et al. in relation to masks and goggles.

5.2.2. Reduced cross-infection control

There are 3 areas in which poor fitting PPE can contribute to reduced cross-infection control; doffing PPE, adjusting PPE and minor injuries caused by ill-fitting PPE. Doffing PPE is a source of concern for health-care workers, but this concern is elevated in a pandemic as improper removal can lead to transmission if the PPE has been contaminated (Zellmer et al., 2015). As reported by the Institute of Medicine, during doffing, self-contamination can occur as microorganisms may be present on the outer surface of the PPE (IoM, 2006). Responses in the current study indicated that time to don and doff is a cause of worry for some who were working in fast-moving or time-critical environments. Some workers had to leave to change PPE several times during a shift and cross infection control during doffing (i.e. removal) was a common concern. Moreover, given the sex-based differences in appropriately fitting PPE, women's susceptibility to cross-infection from poor fitting PPE is of serious concern.

Healthcare workers experience high rates of contamination and the doffing process may be hazardous (Kundrapu et al., 2016) and as such appropriate procedures must be in place. During the SARS-CoV epidemic of 2003, healthcare workers were required to wear double layers of gowns, gloves, masks and head and foot coverings, removing the outer layer to venture into 'clean' areas (Chen et al., 2009), thus adding to the doffing load and the potential for contamination. Even with formal processes, as one respondent to the current survey commented, "The whole process of donning and doffing, and supporting colleagues to do so, slows work flow down and is tiring, although essential. It's so easy to make donning/doffing mistakes when tired." So, whilst the presence of

COVID-19 might incentivise PPE wearers to adhere more strictly to formal doffing procedures, physical exhaustion and mental fatigue may take its toll and lead to mistakes.

A key area that has yet to be addressed in the literature lies around the doffing of modified PPE. Where doffing procedures do exist and are applied, these only address unmodified PPE. Public Health England (PHE) released specific COVID-19 guidance for donning and doffing PPE, for example, doffing PPE involving a surgical gown for 'aerosol generating procedures' (PHE, 2020b). However, when PPE has been taped down, cut, adjusted, over-tightened or knotted, as per the qualitative findings in this study, these procedures may no longer prove appropriate, or indeed safe. For example, guidance requires gloves to be the first item removed, but if thumb holes have been cut into gowns or glove to gown interfaces have been secured with tape, the gown may need to be partially doffed first. Or, as a further example, part 4 of the guidance advises wearers to "not touch the front of the respirator" but this may not be possible if clips and tape have been used to aid security, comfort or fit. There is currently no guidance for the doffing of modified PPE as to have it would endorse the occurrence of modifications and as such, force recognition that PPE fit is substandard.

Key results included a clear indication that surgical masks, in particular, did not fit around half of the population. This lack of fit leads to continual adjustment, whether the fit is too large or too small, with the consequence of increased face-touching and therefore, potential for contamination. Another set of adjustments concerns visors, goggles and masks where ties or elastics wrap around the head or ears. Slippage of tapes or elastic can require clips or home-made securing devices to be introduced, often as non-disposable items, when the PPE they are securing are considered disposable.

Images of healthcare workers presenting with mask-shaped bruises and abrasions to their face have been distributed via social media worldwide during the COVID-19 pandemic. In this study, 31.1% (n = 34) of respondents suffered from digging in, rubbing or chafing of their FFP2/3 mask. Ongoing use of tight or over-tightened (due to oversize) masks and other PPE can lead to broken skin, burns and sores as reported qualitatively by responders. Not only is this likely to reduce the worker's desire to attend their workplace (Damery et al., 2009), and the likeliness of them donning PPE correctly in future, it may also put the person in unnecessary danger of contamination.

5.2.3. Hampering and affecting work

PPE can hamper healthcare workers in their role, but this is more prevalent where PPE fit is less than optimal. The TUC report of 2017 confirmed that unsuitable PP can have an "impact on a person's work and their safety" with 57% of women advising that their PPE hampered their work to some degree (TUC, 2017). As presented in section 4.1.1, over half (55.7%) of respondents reported that their PPE hampered their work, consistent with TUC findings. It was notable for this study, that there were no discernible differences when comparing women and men. However, qualitative narratives occur in pockets: for example, women who voluntarily described themselves as large chested and of shorter stature, when wearing a visor, found issues around impingement of visors on the chest area when the head was moved downwards.

In this study qualitative results also indicated that, whilst provided in line with current policy and standards, PPE may not be practical across all healthcare settings, with mental health settings being a prime example. One mental health worker summarized the issues: "Within mental health settings when patients are unwell, they might not have capacity to understand the social distancing rules or they present with behaviors putting themselves and staff at a higher risk." She went on to suggest that "mental health staff may need more robust masks, eye protection, etc. to manage this safely."

Current guidelines for COVID-19 are the same for a range of healthcare settings, with "Acute hospital inpatient and emergency departments, mental health, learning disability, autism, dental and maternity settings" all adhering to the same set of PPE recommendations

(PHE, 2020a). Many respondents gave qualitative examples, from aprons and gowns interfering when moving patients from bed-to-bed, goggles and visors misting up, and to not being able to communicate. These difficulties have yet to be investigated in detail, but literature does point to an ongoing issue with communication once face-based PPE is donned. In their 2014 study, Locatelli et al. reported from the patients' perspective; patients believe that they should be able to see their caregivers' "facial expressions during interactions" (Locatelli et al., 2014) and this was a common thread in the qualitative feedback. As expressed by a mental health worker, this is intensified in mental health locales as patients are not able "to see our mouth or facial expressions causing increased paranoia and anxiety. [We are] also unable to give reassurance through a smile." The reduction in ability to communicate verbally and non-verbally with patients and other team members whilst wearing PPE was an issue across many settings, and especially so for those dealing with patients who needed to lip read. Healthcare workers want to be safe, but they also want to communicate effectively with their patients and their co-workers, which at times requires a vital human touch. They don't wish the patient to be scared or anxious and they recognise that removing the ability of the patient to see their face prevents them from doing their job in full. Patient care is also affected when morale is reduced through uncomfortable PPE, specifically when carrying out bedside procedures in healthcare settings (Or et al., 2018).

Locatelli et al. agree that "Improving fit, comfort and tolerability has the potential to increase wear incidence and improve patient outcomes" (Locatelli et al., 2014).

5.3. Survey limitations

It is appreciated that sample size, whilst believed to be the largest targeted survey of its kind, would have benefited from being larger. It is notable that the difference in population size between women and men is four-fold and it is acknowledged that small changes in responses for women can have significant impact on results where reported by percentage. It is also noted that bias introduced to respondents by media reports during the COVID-19 outbreak has not been measured, nor accounted for, within this survey.

A further consideration concerns the unexpected amount of qualitative responses volunteered by respondents, including from opportunities to add additional comments. These responses have been included here due to their contextual relevance and importance.

6. Conclusions and future work

This study aimed to investigate previously reported issues with PPE fit, including sex differences, in healthcare settings. A survey of 248 healthcare workers, across a range of settings, revealed significant fit and tolerability problems. Many suffered from over or under sized PPE, with over a third of all respondents modifying their PPE to create a better fit. There were clear sex differences for some items of PPE. Over half of respondents (55.7%) experienced being hampered in their role in some way, with no statistically significant sex differences in this regard. Less than a third of women felt safe in their roles during the pandemic, compared with more than half of men.

Disposable aprons were large for nearly a quarter of women and approximately 15% of men. Surgical gowns were worse fitting for women with over half finding them large to some extent (men less than 15%). Over half of all respondents had fit issues with their surgical scrubs (no major sex differences). Face covering PPE exhibited further issues; surgical masks were also more problematically large for over half of the women that responded but more than a quarter of men found them large too. Around half of women wearing FFP masks had fit problems as did over a third of men. Nearly three quarters of men found their visor fit well, compared with less than half of women. Over a third of women found their goggles or glasses were too large (less than 15% of men).

The importance of considering comfort and tolerability alongside PPE fit was discussed. The unintended consequences of ill-fitting PPE were examined, including the physical outcomes such as facial abrasions; the reduction of cross infection control, partly due to the unregulated doffing of modified PPE; hampering of healthcare workers in their roles, including reduced patient and peer communication (and as a result, patient outcomes) as a consequence of face covering PPE.

This research has outlined the clear need for a change in PPE provision in healthcare settings. Fit, comfort, healthcare setting and role specific requirements must all be considered; the existence of the COVID-19 pandemic has exacerbated many issues.

In future, a more expansive qualitative survey is recommended, to obtain a broader view of setting-based requirements and understand more about how current PPE can be role limiting. The effect of qualitative exploration can be more thoroughly engaged and followed up on, given the responses in the current study indicated a broad range of issues. Such a study would be extensive, targeted nationally, supported by the Health Research Authority, and distributed in a formal, structured manner by an industry-led working group that would build upon the findings of this paper. It must be recognized that even within a given role

and setting, workers needs are not necessarily the same (Shah and Robinson, 2006). Patient input is also essential; conversations around PPE are seemingly devoid of patient involvement. However, this is critical to ensure improved outcomes for patients and not just for the wearers.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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Appendix I

Table iRole of respondents (themed)

Role	No. of Responses
Nurse	75
Healthcare Assistant (HCA)	34
Doctor (non-General Practitioner)	25
Senior Nurse	23
Allied Health Professional (AHP)	22
Consultant	13
Midwife	12
Management	11
General Practitioner (GP)	7
Senior Management	7
Pharmacist	6
Practice Nurse	4
Admin	3
Other	3
Dentist	2

Table iiHealthcare setting of respondents

Healthcare Setting	No. of Responses
Hospital	152
Mental health facility	53
Community	13
GP surgery	13
Other	10
Residential/Nursing/Care home	7

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